

08/897,441


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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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M 5552,0953-04

EXAMINER

HM12/0516

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ART UNIT 121508.3

DATE MAILED 642

05/16/00

 This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

**OFFICE ACTION SUMMARY**
☒ Responsive to communication(s) filed on July 31, 1998
☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**
☒ Claim(s) 5-7, 9-12, 14-23 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 5-7, 9-12, 14-23 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**
☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**
☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 → replace with previous 948 was for a different application

☐ Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

1. Claims 5 and 10 have been amended.  
Claim 8 has been canceled.  
Claims 5-7, 9-12 and 14-23 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The rejection of claim 10 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.
4. The rejection of claim 5, 17 and 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.
5. The rejection of claims 7 and 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,712,370 is maintained. Additionally, claims 6, 11, 17, 18, 20 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,712,370. Although the conflicting claims are not identical, they are not patentably distinct from each other because the monoclonal antibodies of claims 1 and 2 of U.S. Patent No. 5,712,370 anticipate the broadly claimed "antibodies" of claims 6 and 17-18 and the diagnostic aids and pharmaceutical compositions of claims 11 and 20-21, whose only identified components are said antibodies.
6. The rejection of claims 5, 6, 10-12, 18, and 23 under 35 U.S.C. 102(b) as being anticipated by Lin (US PN 4,703,008) is withdrawn. The rejection of claims 17, 20 and 22 under 35 U.S.C. 102(b) as being anticipated by Lin (US PN 4,703,008) is maintained. It is noted that claims 17, 20 and 22 are broadly drawn to antibodies "directed against epitopes that binds

(sic) to the EPO receptor" and are not limited to any specific peptide and need not neutralize the biological activity of EPO. Thus, more likely than not, one of the three antibodies disclosed in col.36 (all generated by immunization with peptides 41-57, 116-128 or 144-166, and all of which immunoprecipitate intact EPO) binds to a region of EPO that interacts with the EPO receptor and is the same as that claimed.

7. The rejection of claims 9, 14-16 under 35 U.S.C. 103(a) as being unpatentable over Lin (US PN 4,703,008) is withdrawn. The rejection of claim 21 under 35 U.S.C. 103(a) as being unpatentable over Lin (US PN 4,703,008) is maintained. Applicant argues that "the obviousness of storing Lin's antibodies in pharmacologically acceptable form is irrelevant to the issue of whether the claimed antibodies, pharmaceutical compositions and diagnostic aids would have been obvious to one of skill in the art" is not found persuasive. Applicant is referred to the above paragraph, which explains that Lin's antibodies are the same as the claimed antibodies.

#### NEW REJECTIONS

8. Claims 5, 9, 12, 14-16 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "142 to 166 (P2) in claim 5 is vague and indefinite. It is noted that the specification has been amended to recite "138 to 166 (P2)." Thus, the identity of the start point of the claimed P2 peptide is ambiguous. For examination purposes, claims 5, 12 and 23 are interpreted as written, as being drawn to a P2 peptide of "142 to 166."

In view of the cancellation of claim 8, claims 9 and 14-16, all of which depend from claim 8, are vague and indefinite.

9. Claims 9 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specificity of the antibodies of claims 9 and 14-16 is defined by claim 8, which has been canceled. Absent limitations defining the specificity of the claimed anti-idiotypic antibodies, one of skill in the art can not predictably make and use the claimed antibodies without undue experimentation.

10. Claims 17, 18, 20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sytkowski (J.B.C. 262:1161, 1987). Sytkowski discloses antibodies generated by immunization with EPO peptides 99-118 and 111-129 which bind to EPO and neutralize EPO activity (thus, more likely than not these antibodies bind to rejoin of EPO that interact with the EPO receptor, see col.1, p. 1164) and are the same as that claimed. Sytkowski also discloses a method of purifying EPO by using said antibodies (via immunoprecipitation) that is the same as that claimed in claim 22.

11. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sytkowski (J.B.C. 262:1161, 1987). The teachings of Sytkowski, of antibodies that bind to EPO, is discussed in the paragraph above. Sytkowski does not teach monoclonal antibodies or pharmaceutical antibodies. However, both such modifications are well known and standard to one of skill in the art, once an antibody has been generated.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 15, 2000



NANCY A. JOHNSON, PH.D  
PRIMARY EXAMINER